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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/676,176	10/01/2003	Fredrik Solhage	ANO 6277 US/3166	6797

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EXAMINER	
ISSAC, ROY P	
ART UNIT	**PAPER NUMBER**
1623	

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11/29/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/676,176	SOLHAGE ET AL.	
	Examiner	Art Unit	
	Roy P. Issac	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 October 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3,5,6,8-12,14,15,17-22,25,26 and 29-36* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3,5,6,8-12,14,15,17-22,25,26 and 29-36* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/15/2007 has been entered.

Applicants' submission in which claims 4, 7, 13, 16, 23, 24, 27 and 28 have been cancelled, claims 1, 11, 19, 21 and 25 have been amended, and claims 29-36 have been newly submitted is acknowledged.

Rejections Withdrawn

In view of the cancellation of claims 4, 7, 13, 16, 23, 24, 27 and 28, all rejections made with respect to claims 4, 7, 13, 16, 23, 24, 27 and 28 in the previous office action are withdrawn.

The insertion of formulae I and II in claims 1 and 11 overcomes the scope of enablement rejection of claims 1-3, 5-6, 8-12, 14-15 and 17-19 and the rejection under section 112, first paragraph of claims 1-3, 5-6, 8-12, 14-15 and 17-19 is withdrawn.

The insertion of formulae I and II in claims 1 and 11 overcomes the indefiniteness rejection of claims 1-3, 5-6, 8-12, 14-15 and 17-19 and the rejection under section 112, second paragraph of claims 1-3, 5-6, 8-12, 14-15 and 17-19 is withdrawn.

Claim Objections

Claims 20, 30 and 32 are objected to because of the following informalities: Claim 20, 30 and 32 recites the range "0,02 to 0,5" in which a comma is used in place of a period. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 21-22, 25-26 and 29-36 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for substituents $-CH_2$-$CH(OH)$-CH_2-$N^+((CH_3))_2)CH_2C_6H_5$ Cl-, and $-CH_2$-$CH(OH)$-CH2-$N^+((CH_3)_3)$Cl-, does not reasonably provide enablement for **any** aromatic or **any** non-aromatic substituents. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The instant specification fails to provide information that would allow the skilled artisan to practice the instant invention. Attention is directed to *In re Wands*, 8 USPQ2d

1400 (CAFC 1988) at 1404 where the court set forth the eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing *Ex parte Forman*, 230 USPQ 546 (BdApls 1986) at 547 the court recited eight factors:
(1) the nature of the invention; (2) the state of the prior art; (3) the relative skill of those in the art; (4) the predictability or unpredictability of the art; (5) the breadth of the claims; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary.

Nature of the invention:

The instant application relates the cationization of polysaccharides with two quaternary amine substituents, one with an aromatic group and another without an aromatic group.

The relative skill of those in the art:

The relative skill of those in the art is high, with a typical practitioner having obtained a PhD, M.S. or equivalent advanced degree.

The breadth of the claims:

The instant claims are deemed very broad because they encompass any of the millions of substituents that can be considered either aromatic or non-aromatic. Claims where aromatic group is describes as "group containing 1 to 12 carbon atoms" encompass thousands of permutations of which only one is exemplified in the instant application.

The amount of direction or guidance presented and the presence or absence of working examples:

The instant application exemplifies polysaccharides cationised with two substitutents, the aromatic substituent $-CH_2-CH(OH)-CH_2-N^+((CH_3))_2)CH_2C_6H_5$, and the non-aromatic substituent $-CH_2-CH(OH)-CH2-N^+((CH_3)_3)Cl-$. The specification further describes varying degrees of substitution of the two groups. However, no other substituent is exemplified. The term aromatic encompass a wide range of compounds with diverse properties, including varying reactivity, solubility and functionality. The operability of one particular aromatic substituent does not predict the operability of all other aromatic substituents. Similarly, the term non-aromatic group is also a description that encompasses a wide variety of groups with varying properties. Some examples of non-aromatic substituents include carbohydrates, lipids and long chain alkyl polymers, all of which have divergent chemical and physical properties. As such, one of skill in the art would not expect any substituents other than ones with strong structural similarity to the ones exemplified to function similarly.

"Aromatic implies various features, properties, or behaviors to chemists with different backgrounds." (Schleyer PV. Chemical Reviews, 2001, 1115-1117, Page 1117, Column 2, Paragraph 3; Of Record). The term aromatic despite its use in the literature is nonreductive. "They have no precise meaning and do not denote directly mreasurable quantities." (Page 1115, Column 1, Paragraph 3). They encompass large groups of compounds that often have dissimilar properties. For example, there are nonbenzenoid aromatics. Some of the compounds are negatively charged. (Page

1115, Column 2, paragraph 2). Some are heterocyclic while others are transition metal complexes. Different physical properties do not necessarily correlate with aromaticity criteria. (Page 1116, Column 2, Paragraph 3). Some of the heterocyclic complex are difficult to evaluate. (Page 1117, Column 1, Paragraph 1). In view of the complexity and breadth of "aromatic" compounds, the applicant have not enabled one of skill in the art to practice the invention in the full scope of the claims herein.

The lack of working examples is a critical and crucial factor to be considered, especially in cases involving an unpredicatable and undeveloped art. See MPEP § 2164.

The predictability or lack thereof in the art and the quantity of experimentation necessary:

Organic synthesis in particular is a very unpredictable art. Some of the synthesis efforts in organic chemistry take years to complete, often an exercise in trial and error. The generic claims in the instant application encompass thousands of compounds with wide varying functional groups. The additional groups claimed by the generic formula have well-established divergent function and properties.

Thus, the specification fails to provide clear and convincing evidence in sufficient support of the claimed compounds in their full scope described by the terms "aromatic group" and "non-aromatic" group.

Genentech, 108 F.3d at 1366, sates that, "a patent is not a hunting license. It is not a reward for search, but compensation for its successful conclusion." And "patent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable."

Therefore, in view of the *Wands* factors as discussed above, to practice the claimed invention herein, a person of skill in the art would have to engage in ***undue experimentation*** to practice the invention commensurate in scope with the claims.

Response to Arguments

Applicant's arguments filed 10/15/07 have been fully considered but they are not persuasive. Applicants argue that a large number of working examples are not necessary and that the claims specifically do not need to exclude inoperative substances. However, the breadth of enablement herein is not commensurate in scope with the claims. The scope of the claims as amended encompass substituents including "aromatic groups" and a "second substituent having no aromatic group". The amount of direction presented and the number of working examples provided in the specification were very narrow compared to the wide breadth of the claims at issue. The applicants argue that the enablement rejections based on broadness of claims is improper. The breadth of the claims is one of the factors considered in rejections under 35 U.S.C 112, first paragraph. However, the examiner has included a Wands analysis that addressed factors beyond broadness of claims, including the amount of direction or guidance presented, the presence or absence of working examples, the predictability or lack

thereof in the art and the quantity of experimentation necessary. (See pages 4-6 of the previous office action). The conclusion that a person of skill in the art would have to engage in undue experimentation to practice the invention commensurate in scope with the claims is reached in consideration of the several factors discussed in the previous office action, including the breadth of the claims. Applicants further argue that applicants descriptions such as "the substituents can be attached by a heteroatom", and the listing of a few preferred and more preferred substituents in the specification provides enablement for the full scope of the claimed encompassed by the terms "aromatic" and "non-aromatic". In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., the preferred and more preferred aromatic substituents) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Applicants further assert that, a large number of working examples are not necessary. The terms "aromatic" and "non-aromatic" together describes almost all imaginable substituents in organic chemistry. As pointed out in the previous office action, the instant application only exemplify polysaccharides cationised with two substitutents, the aromatic substituent $-CH_2-CH(OH)-CH_2-N^+((CH_3))_2)CH_2C_6H_5$, and the non-aromatic substituent – CH_2-CH(OH)-CH2-$N^+((CH_3)_3)$Cl-. No working examples of any hetero-aromatic functionalities or lipids or carbohydrates provided. In applications directed to inventions in arts where the results are unpredictable, the disclosure of a single species usually

does not provide an adequate basis to support generic claims. (See *In re Soll*, 97 F.2d 623, 624, 38 USPQ 189, 191 (CCPA 1938)). In cases involving unpredictable factors, such as most chemical reactions and physiological activity, more may be required. (See *In re Fisher*, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970) (contrasting mechanical and electrical elements with chemical reactions and physiological activity). See also In re Wright, 999 F.2d 1557, 1562, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993); In re Vaeck, 947 F.2d 488, 496, 20 USPQ2d 1438, 1445 (Fed. Cir. 1991)). This is because it is not obvious from the disclosure of one species, what other species will work. In view of the complexity and breadth of the terms "aromatic" and 'non-aromatic" compounds, representing almost all of the organic substituents, the applicants have not enabled one of skill in the art to practice the invention in the full scope of the claims herein.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 21-22, 25-26, 31-32 and 35-36 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The recitations "substituent having an aromatic group" and a "substituent having no aromatic group" renders the claim indefinite. The recited phrases do not convey a structural formula or chemical

name to one of ordinary skill in the art. In the absence of a structural formula or chemical name, the claims reading on "substituent having an aromatic group" and "substituent having no aromatic group" wherein each variables are not distinctly claimed are indefinite as one of skill in the art would not be apprised of the metes and bounds of claimed invention.

No response/ arguments were filed over the above rejection under 35 U.S.C 112, second paragraph.

Rejection under 35 U.S.C. 112 second paragraph of claims 21-22, 25-26, 31-32 and 35-36 is still deemed proper and is adhered to.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

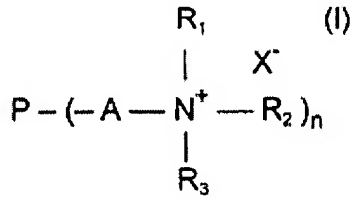
Claims 1-3, 5-6, 8-12, 14-15, 17-22, 25-26 and 29-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Matsunaga et. al. (JP 62149702, English Translation; Of record), in view of Persson et. al. (WO 99/55964;Of record).

Matsunaga et. al. discloses 3-chloro-2-hydroxypropyl trimethylammonium chloride (CMT) adduct of polysaccharide that further contains varying ranges of benzyl

adduct. (Page 9, Table 1). Note that the 3-chloro-2-hydroxypropyl trimethylammonium chloride is the same non-aromatic substituent exemplified in the instant application. The polysaccharide from corn starch has a 2:1 ratio of non-aromatic to aromatic substituent, while for tapioca, the ratio is 5:4, and for potato it is 3:4.7. (Table 1). Matsunaga discloses 6.5-10% substitution of CTA and 3-5% substitution of the aromatic group, benzyl chloride. The degree of cationization ranged from 3.9% to 6.0%. (Table 1). These ranges fall within the claimed ranges herein. Matsunaga further discloses a criteria for selecting substituents to prevent resolidification in paper manufacturing. (Page 2-3). The criteria includes the selection of a group with a high molecular weight and bulky structure, high boiling point. Matsunaga et. al. elects the benzyl as a group that meets this criteria in making benzyl substituted polysaccharides. (Page 4, lines 18-25). Benzyl chloride was added with CTA simultaneously to polysaccharide containing solution to get polysaccharides substituted with both groups. Even though Matsunaga does not report the charge density of the composition, it is expected to have the same charge density as the instant application because the compositions' substitution range falls within the instant application.

Matsunaga et. al. does not expressly disclose a cationized aromatic substituent or the use of the particular aromatic quaternary amine substituent of the general structure I of the instant application. Matsunaga et. al. does not disclose substitutents wherein R1, R2 and R3 together with N forming an aromatic group containing 5-12 carbon atoms.

Persson et. al. discloses cationised polysaccaharides with quaternary ammonium substituents. The cationized polysaccharides have the following structure, as disclosed in the instant application including the particular substituents exemplified in the instant application. (Page 4, lines 3-25).



(I)

Persson et. al. discloses 2-hydroxypropyl dimethyl benzyl ammonium chloride (a cationic substituent having an aromatic group) as one of the hydrophobic substituents for polysaccharides. (Example 1, Page 11, lines 20-30). Persson et. al. discloses substituents where R1, R2 and R3 together with N form an aromatic group containing 5-12 carbon atoms. Presson et. al. discloses two polysaccharide polymers each individually having the particular substituents of the instant applicaton. (Page 11, Example 1, compounds P1 and Ref 1). Persson et. al. further discloses epichlorohydrin as a suitable modifying agent.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to synthesize a polysaccharide with a first substituent comprising –CH2-CH(OH)-CH2-N^+((CH3)2)CH2C6H5 Cl- and the second substituent -CH2-CH(OH)-CH2-N^+((CH3)3)Cl-, because Matsunaga et. al. discloses a polysaccharide with two types of substituents, one aromatic and one non-aromatic as claimed herein, and Persson et. al. discloses the particular aromatic substituent –CH2-CH(OH)-CH2-

$N^+((CH3)2)CH2C6H5$ Cl- for polysaccharides. Note that, independent claims 21 and 25 are in the product-by-process format. These two claims appear to give rise to the same products claimed in claims 1-20.

One of ordinary skill in the art would have been motivated to use the particular substituents of the instant application because Matsunaga et. al. discloses polysaccharides with two types of substituents, one particular substituent (non-aromatic) identical to the instant application, and the other structurally similar to the one claimed herein, well known for use as substituent in polysaccharide paper production by Persson et. al. If the claimed invention and the structurally similar prior art species share any useful property, that will generally be sufficient to motivate an artisan of ordinary skill to make the claimed species. It is a reasonable expectation that similar species usually have similar properties. See Dillon, 919 F.2d at 693, 696, 16 USPQ2d at 1901, 1904. See also, Deuel, 51 F.3d at 1558, 34 USPQ2d at 1214. In fact, similar properties may formally be presumed when compounds are very close in structure. Dillon 919 F.2d at 693, 696, 16 USPQ2d at 1901, 1904, as noted in MPEP 2144. Herein, all claimed elements were known in the prior art and one skilled in the art could have combined the elements as claimed by known methods with no change in their respective functions, and the combination would have yielded predictable results to one of ordinary skill in the art at the time of the invention. The substitution of one element for another, an aromatic substituent with a cationized aromatic substituent, would have yielded predictable results to one of ordinary skill in the art at the time of the invention. One of ordinary skill in the art would have reasonably expected that the substitution of –

CH2-CH(OH)-CH2-N^+((CH3)2)CH2C6H5 Cl- instead of benzyl chloride would have resulted in polysaccharide with beneficial properties in paper production.

As such, the invention is prima facie obvious over the combined teachings of the prior art.

Response to Arguments

Applicant's arguments filed 10/15/2007 have been fully considered but they are not persuasive. Applicants argue that, in comparison to cationic starch the polymers of the instant claims have significantly higher burst strength index which the applicants submit as unexpected results. It is applicant's burden to demonstrate unexpected results over the closest prior art. See MPEP 716.02, also 716.02 (a)-(g). Furthermore, the unexpected results should be demonstrated with evidence that the differences in results are in fact unexpected and unobvious and of both statistical and practical significance. *Ex Parte Gelles,* 22 USPQ2d 1318, 1319 (Bd. Pat. App & Inter. 1992). Moreover, evidence as to any unexpected benefits must be "clear and convincing". *In re Lohr*, 137 USPQ 548 (CCPA 1963), *In re Linder,* 173 USPQ 356 (CCPA 1972). Herein the closest prior art is the polymers of Matsunaga et. al with both cationic non-aromatic and non-ionic aromatic substituents. Applicants further argue that Matsunaga teach away from adding additional cationizing agent to startch that was cationized with CTA. However, the cited passage does not teach away from using any additional cationozing agent other than CTA. The cited passage merely discloses that it is uneconomical to use cations that are necessary. It doesn't teach away from using

cationized aromatic subtituent along with cationized non-aromatic substituent. In fact, one of ordinary skill in the art would view the use of cationized aromatic substiuent in place of the non-ionic aromatic substituent as a way to reduce the use of CTA. Applicants argument that Matsunaga teaches away from substituting cationized aromatic substituent was found unpersuasive. The rejection under section 103 is still deemed proper and is adhered to.

No Claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Roy P. Issac whose telephone number is 571-272-2674. The examiner can normally be reached on 9:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia Anna Jiang can be reached on 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

11/24/07

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